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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,727	01/18/2005	Antonio Mete	06275-430US1/100772-1P US	2245
26164 7590 10/15/2007 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CHUNG, SUSANNAH LEE	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/521,727	Applicant(s) METE ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/24/05, 6/29/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-4, 6, and 13-21 are pending in the instant application. Claims 5 and 7-12 are canceled.

#### ***Priority***

This application is a 371 of PCT/SE03/01215, filed 07/15/2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. 0202279-6 filed in the Swedish Patent Office on 7/19/2002, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS), filed on 03/24/05 and 6/29/07 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Response to Election/Restrictions***

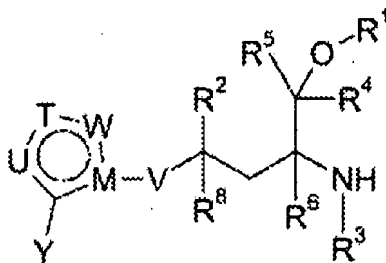
Applicant's election without traverse of Group I, claims 1-4 and 6, in the reply filed on 9/24/2007 is acknowledged.

#### ***Scope of the Elected Invention***

Claims 1-4, 6, and 13-21 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows:

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Compounds of formula (I),

, depicted in claim 1, page 3

of 10, wherein:

**T, W, and M** are C;**U** is S;

**V** is S preferably, NR<sub>7</sub>, O, CH<sub>2</sub>, S(O)<sub>n</sub>, OCH<sub>2</sub>, CH<sub>2</sub>O, NR<sub>7</sub>CH<sub>2</sub>, CH<sub>2</sub>NR<sub>7</sub>, CH<sub>2</sub>S(O)<sub>n</sub>, S(O)<sub>n</sub>CH<sub>2</sub>, CH<sub>2</sub>CH<sub>2</sub> or CH=CH.

### *Scope of Withdrawn Subject Matter*

Claims 13-21 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Germane, et al (Khimiko-Farmatsevticheskii Zhurnal, 10(10), 1976, pages 16-21).

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Applicants claims relate to compound of Formula (I) in claim 1. Germane discloses compounds that anticipate the instantly claimed genus wherein: **T, W, and M** are C; **U** is SO<sub>2</sub>; **V** is N; **Y** is halogen; and **R1, R2, R3, R4, R5, R6 and R8** are hydrogen. (See Abstract, CAS RN 62268-34-2, 2-amino-4-[(2-chloro-1,1-dioxidobenzo[b]thien-3-yl)amino]-1-butanol).

### ***Obviousness Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

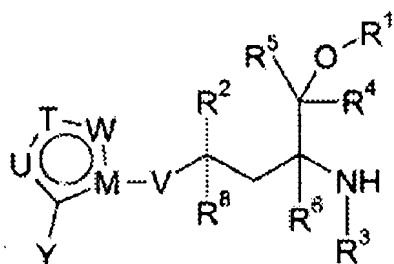
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, and 6 of US Patent Application No. 10/521,728. A notice of allowance was issued for this application on 09/20/2007.

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This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicants instant elected invention discloses the compounds and compositions of

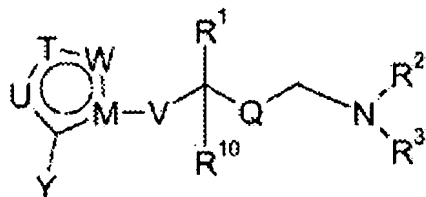


formula (I),

, for treating pain.

Determination of the scope and content of the co-pending application

Co-pending application No. 10/521,727 claims the compound of formula (I),

, wherein Y is CH<sub>2</sub>OH, for treating pain.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between co-pending application no. 10/521,728 and the instant application is that in the co-pending application Y is CH<sub>2</sub>OH, while in the instant application the CH<sub>2</sub>OH moiety is found next to the amino group.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compounds prima facie obvious over the co-pending applications because the instantly claimed compounds are homologues of the copending application. Adjacent homologues and structural isomers are generally so structurally similar that “without more” such structural similarity could give rise to prima facie obviousness.

In re Wilder, 563 F.2d 457, 195 USPQ 426. The co-pending application teaches one of ordinary

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skill in the art how to create the compounds claimed in the instant application. Given the preferred embodiments and the specific embodiments listed in the claims, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Both the instantly claimed compounds and the compounds of the co-pending applications are used to treat pain. Although, the conflicting claims are not identical, they are not patentably distinct from each other because applicant's instantly claimed invention is a homologue of the copending application. Therefore, one skilled in the art would have found the variation obvious when faced with the co-pending applications because the compounds are used for the same pharmacological use so one skilled in the art would expect similar properties and results.

In addition, the doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that: The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent. *In re Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). The instant invention could have been claimed in the copending application because of the similar structure and chemistry involved in making the compounds. Absent a showing of unexpected results, the instantly claimed compounds are obvious over the copending application.

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*Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

*Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

REBECCA ANDERSON  
PRIMARY EXAMINER

Joseph K. McKane  
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Date: 11 October 2007